

Reimbursement of Sexual or Erectile Dysfunction Drugs and Products For Pulmonary Hypertension *REVISED*

On December 22, 2005, an email was sent to all CCS medical directors and consultants advising that only Revatio® should be approved for treatment of pulmonary hypertension, beginning January 1, 2006.

In addition, beginning April 1, 2006, the following drugs were restricted: Viagra®¹, Levitra®, and Cialis®.

These actions were taken to comply with federal legislation (HR 3971) that forbids federal funds for treatment of sexual or erectile dysfunction and only allows for its FDA approved use and Welfare and Institutions Code 14132(d), precluding Medi-Cal coverage without federal financial participation.

To further prevent payment of claims disallowed through the Medi-Cal Program, effective September 14, 2007, the products for sexual or erectile dysfunction listed in the table below have been 'zero-priced'.

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¹ Viagra® and Revatio® have the same generic name, Sildenafil Citrate. CMSNET lists the NDC for brand Revatio® and Sildenafil Citrate Powder, only.

Therefore, claims for these drugs and products will be denied for payment, even with prior authorization from CCS:

| Zero Priced Drugs | | | | |
|-------------------------------|----------------------|--|--|--|
| Product Label Name | Product Generic Name | | | |
| ACTIBINE 5 MG TABLET | YOHIMBINE HCL | | | |
| ACTIBINE 5MG TABLET | YOHIMBINE HCL | | | |
| APHRODYNE 5.4 MG CAPLET | YOHIMBINE HCL | | | |
| CAVERJECT 10 MCG KIT | ALPROSTADIL | | | |
| CAVERJECT 10 MCG VIAL | ALPROSTADIL | | | |
| CAVERJECT 10 MCG/ML AMPUL | ALPROSTADIL | | | |
| CAVERJECT 20 MCG KIT | ALPROSTADIL | | | |
| CAVERJECT 20 MCG VIAL | ALPROSTADIL | | | |
| CAVERJECT 20 MCG/ML AMPUL | ALPROSTADIL | | | |
| CAVERJECT 40 MCG VIAL | ALPROSTADIL | | | |
| CAVERJECT 40 MCG/2 ML AMPUL | ALPROSTADIL | | | |
| CAVERJECT 5 MCG KIT | ALPROSTADIL | | | |
| CAVERJECT IMPULSE 10 MCG KIT | ALPROSTADIL | | | |
| CAVERJECT IMPULSE 20 MCG KIT | ALPROSTADIL | | | |
| CIALIS 10 MG TABLET | TADALAFIL | | | |
| CIALIS 20 MG TABLET | TADALAFIL | | | |
| CIALIS 5 MG TABLET | TADALAFIL | | | |
| DAYTO-HIMBIN 5.4 MG TABLET | YOHIMBINE HCL | | | |
| DAYTO-HIMBIN 5.4 MG/15 ML LIQ | YOHIMBINE HCL | | | |
| EDEX 10 MCG CARTRIDGE KIT | ALPROSTADIL | | | |
| EDEX 10 MCG KIT | ALPROSTADIL | | | |
| EDEX 10 MCG REFILL PACK | ALPROSTADIL | | | |
| EDEX 10 MCG STARTER PACK | ALPROSTADIL | | | |
| EDEX 10 MCG VIAL | ALPROSTADIL | | | |
| EDEX 20 MCG CARTRIDGE KIT | ALPROSTADIL | | | |
| EDEX 20 MCG KIT | ALPROSTADIL | | | |
| EDEX 20 MCG REFILL PACK | ALPROSTADIL | | | |
| EDEX 20 MCG STARTER PACK | ALPROSTADIL | | | |
| EDEX 20 MCG VIAL | ALPROSTADIL | | | |
| EDEX 40 MCG CARTRIDGE KIT | ALPROSTADIL | | | |
| EDEX 40 MCG KIT | ALPROSTADIL | | | |
| EDEX 40 MCG REFILL PACK | ALPROSTADIL | | | |
| EDEX 40 MCG STARTER PACK | ALPROSTADIL | | | |
| EDEX 40 MCG VIAL | ALPROSTADIL | | | |
| EDEX 5 MCG KIT | ALPROSTADIL | | | |
| EDEX 5 MCG VIAL | ALPROSTADIL | | | |
| EREX 5.4 MG TABLET | YOHIMBINE HCL | | | |
| LEVITRA 10 MG TABLET | VARDENAFIL HCL | | | |

| Zero Price | ed Drugs | |
|------------------------------|----------------------------|--|
| Product Label Name | Product Generic Name | |
| LEVITRA 2.5 MG TABLET | VARDENAFIL HCL | |
| LEVITRA 20 MG TABLET | VARDENAFIL HCL | |
| LEVITRA 5 MG TABLET | VARDENAFIL HCL | |
| MEDEREK 5.4 MG TABLET | YOHIMBINE HCL | |
| MUSE 1,000 MCG URETHRAL SUPP | ALPROSTADIL | |
| MUSE 125 MCG URETHRAL SUPPOS | ALPROSTADIL | |
| MUSE 250 MCG URETHRAL SUPPOS | ALPROSTADIL | |
| MUSE 500 MCG URETHRAL SUPPOS | ALPROSTADIL | |
| PROHIM 5.4 MG TABLET | YOHIMBINE HCL | |
| SUPINA NR TABLET | YOHIMBINE HCL | |
| TESTOMAR 5.4 MG TABLET | YOHIMBINE HCL | |
| THYBINE 5.4 MG TABLET | YOHIMBINE HCL | |
| THYBINE 5.4MG TABLET | YOHIMBINE HCL | |
| THYBINE TABLET | YOHIMBINE HCL/STRYCHNINE | |
| VIAGRA 100 MG TABLET | SILDENAFIL CITRATE | |
| VIAGRA 25 MG TABLET | SILDENAFIL CITRATE | |
| VIAGRA 50 MG TABLET | SILDENAFIL CITRATE | |
| VIRIL-LAM 5 MG/5 ML SOLUTION | YOHIMBINE HCL | |
| VIRITAB 5.4 MG TABLET | YOHIMBINE HCL | |
| YOCON 5.4 MG TABLET | YOHIMBINE HCL | |
| YOHIMAR DUOPACK TABLET | YOHIMBINE HCL/ZINC SULFATE | |
| YOHIMBINE 5 MG TABLET | YOHIMBINE HCL | |
| YOHIMBINE 5.4 MG TABLET | YOHIMBINE HCL | |
| YOHIMBINE 5.4MG TABLET | YOHIMBINE HCL | |
| YOHIMBINE 5MG TABLET | YOHIMBINE HCL | |
| YOHIMBINE HCL 5.4 MG TABLET | YOHIMBINE HCL | |
| YOHIMEX 5.4 MG TABLET | YOHIMBINE HCL | |
| YOHIMEX PZ 5.4 MG TABLET | YOHIMBINE HCL | |
| YOMAN 5.4 MG TABLET | YOHIMBINE HCL | |
| YOVITAL 5.4 MG TABLET | YOHIMBINE HCL | |
| YOVITAL 5.4MG TABLET | YOHIMBINE HCL | |

Claims analysis has revealed that some counties continue to approve Viagra (sildenafil citrate), for payment after January 1, 2006. A list of claims will be sent to each involved CCS office for review. Please inform affected pharmacies that any outstanding SAR or legacy authorization for the above products will result in a denial of payment, even with prior authorization.

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For pharmacy providers who are compounding sildenafil citrate solution with Viagra, there is a temporary work-around that can be used until December 27, 2008. Sildenafil Citrate Powder may be authorized and used to compound the solution:

| NDC | Label Name | Generic Name | Legend Ind | Package Qty |
|-------------|------------------------------|--------------------|---------------|-------------|
| 63275996701 | SILDENAFIL CITRATE POWDER | SILDENAFIL CITRATE | Υ | 1 |
| 63275996702 | SILDENAFIL CITRATE POWDER | SILDENAFIL CITRATE | Υ | 5 |
| 63275996704 | SILDENAFIL CITRATE POWDER | SILDENAFIL CITRATE | Υ | 25 |
| 63275996705 | SILDENAFIL CITRATE POWDER | SILDENAFIL CITRATE | Y | 100 |

Addendum

On October 15, 2007, retroactive "zero-pricing" was made effective back to dates of service beginning July 20, 2006 to comply with AB 2885's provisions.

Effective April 15, 2008, all drugs and products classified as belonging in the specific therapeutic category of DRUGS TO TREAT IMPOTENCY (includes the drugs/products in the above Zero Priced Drugs table) when assigned a new NDC, will automatically be assigned a non-benefit indicator by the Medi-Cal Program. Accordingly, any CCS and GHPP claim billing zero-priced or non-benefit coded NDCs will deny payment, regardless of the presence of an approved SAR.

Additional NDCs are now available to pharmacy providers (beyond the December 27, 2008, date of service as noted above) who will be compounding sildenafil citrate solution:

| Product Number | Product Number Description | Generic Name | Package Size | Medi-Cal Billing Unit |
|-------------------|----------------------------|--------------|-----------------|--------------------------|
| | SILDENAFIL CITRATE | SILDENAFIL | 0.20 | |
| 51552117201 | POWDER | CITRATE | 1 | GRAMS |
| | SILDENAFIL CITRATE | SILDENAFIL | | |
| 51552117202 | POWDER | CITRATE | 5 | GRAMS |
| | SILDENAFIL CITRATE | SILDENAFIL | | |
| 51552117204 | POWDER | CITRATE | 25 | GRAMS |
| | SILDENAFIL CITRATE | SILDENAFIL | | |
| 51552117205 | POWDER | CITRATE | 100 | GRAMS |

Should you have any questions, contact the CMS Branch Pharmaceutical Consultant.